



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Sternberg et al.

Application No. 10/530,254

Filed: April 4, 2005

Confirmation No. 5499

For: METHODS AND FORMULATIONS
COMPRISING AGONISTS AND
ANTAGONISTS OF NUCLEAR
HORMONE RECEPTORS

Examiner: Not yet assigned

Art Unit: 1646

Attorney Reference No. 4239-66912-02

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Attorney or Agent
for Applicant(s)

Date Mailed April 3, 2006

TRANSMITTAL LETTER

Enclosed for filing in the application referenced above are the following:

- ☒ Information Disclosure Statement
- ☒ Form 1449 and references cited thereon
- ☒ The Director is hereby authorized to charge any additional fees that may be required, or credit over-payment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.
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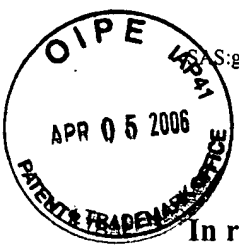
Respectfully submitted,

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PATENT

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**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. § 1.97(b)(3)**

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Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Copies of United States patents and United States published patent applications do not have to be provided to the Patent Office (37 C.F.R. 1.98(a)(2)(ii)). Copies of unpublished U.S. applications do not have to be provided, as long as the application is available on PAIR, as this requirement of 37 C.F.R. § 1.98(a)(2)(iii) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on October 19, 2004 (1287 OG 163). Applicants will provide copies of such patents or applications upon request.

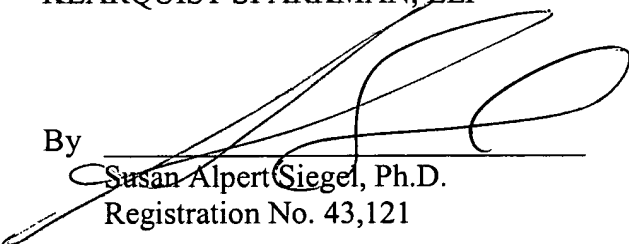
Applicants filed this Information Disclosure Statement ("IDS") before the mailing date of a first Office action on the merits. As a result, no fee should be required to file this IDS. However, if the Patent Office determines that a fee is required for Applicants to file this IDS, authorization to charge any such fees to Deposit Account No. 02-4550 is provided on the accompanying transmittal letter.

The filing of this IDS shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. §1.56.

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First Named Inventor	Esther M. Sternberg
Art Unit	1646
Examiner Name	To be assigned

U.S. PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		5,006,330	09 Apr 1991	Sternberg <i>et al.</i>
		5,677,274	14 Oct 1997	Leppla <i>et al.</i>
		US2003/0207833 A1	06 Nov 2003	Berkley <i>et al.</i>

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		WIPO/PCT	WO 98/26783	25 June 1998	Hoechst Marion Roussel
		WIPO/PCT	WO 98/27986	02 July 1998	Zymogenetics, Inc.
		WIPO/PCT	WO 99/50439	07 Oct 1999	The Government of the United States of America as Represented by the Secretary, Department of Health and Human Services
		WIPO/PCT	WO 01/21656	29 Mar 2001	The Government of the United States of America as Represented by the Secretary, Department of Health and Human Services

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Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS	
		ARORA <i>et al.</i> , "Fusions of anthrax toxin lethal factor to the ADP-ribosylation domain of Pseudomonas exotoxin A are potent cytotoxins which are translocated to the cytosol of mammalian cells," <i>The Journal of Biological Chemistry</i> 267(22):15542-15548, 1992	
		ARORA <i>et al.</i> , "Residues 1-254 of anthrax toxin lethal factor are sufficient to cause cellular uptake of fused polypeptides," <i>The Journal of Biological Chemistry</i> 268(5):3334-3341, 1993	
		ARORA <i>et al.</i> , "Fusions of anthrax toxin lethal factor with shiga toxin and diphtheria toxin enzymatic domains are toxic to mammalian cells," <i>Infection and Immunity</i> 62(11):4955-4961, 1994	
		ARORA <i>et al.</i> , "Cytotoxic effects of a chimeric protein consisting of tetanus toxin light chain and anthrax toxin lethal factor in non-neuronal cells," <i>The Journal of Biological Chemistry</i> 269(42):26165-26171, 1994	
		BHATNAGAR <i>et al.</i> , "Calcium is required for the expression of anthrax lethal toxin activity in the macrophagelike cell line J774A.1," <i>Infection and Immunity</i> 57(7):2107-2114, 1989	
		BHATNAGAR <i>et al.</i> , "Protein synthesis is required for expression of anthrax lethal toxin cytotoxicity," <i>Infection and Immunity</i> 62(7):2958-2962, 1994	
		BHATNAGAR <i>et al.</i> , "Anthrax toxin," <i>Clinical Reviews in Microbiology</i> 27(3):167-200, 2001	
		BLEDSOE <i>et al.</i> , "Crystal structure of the glucocorticoid receptor ligand binding domain reveals a novel mode of receptor dimerization and coactivator recognition," <i>Cell</i> 110:93-105, 2002	
		BRADLEY <i>et al.</i> , "Identification of the cellular receptor for anthrax toxin," <i>Nature</i> 414:225-229, 2001	
		CASTAGLIUOLO <i>et al.</i> , "Endogenous corticosteroids modulate Clostridium difficile toxin A-induced enteritis in rats," <i>Am J Physiol Gastrointest Liver Physiol</i> 280:G539-G545, 2001	
		CHAUDRY <i>et al.</i> , "Quickening the pace of anthrax research: three advances point towards possible therapies," <i>Trends in Microbiology</i> 10(2):58-62, 2002	
		DUESBERY <i>et al.</i> , "Proteolytic inactivation of MAP-kinase-kinase by anthrax lethal factor," <i>Science</i> 280:734-737, 1998	
		DUESBERY <i>et al.</i> , "Anthrax lethal factor causes proteolytic inactivation of mitogen-activated protein kinase kinase," <i>Journal of Applied Microbiology</i> 87:289-293, 1999	

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		DUESBERY <i>et al.</i> , "Suppression of ras-mediated transformation and inhibition of tumor growth and angiogenesis by anthrax lethal factor, a proteolytic inhibitor of multiple MEK pathways," <i>Proc. Natl. Acad. Sci. USA</i> 98(7):4089-4094, 2001	
		EDWARDS <i>et al.</i> , "The pituitary gland is required for protection against lethal effects of Salmonella typhimurium," <i>Proc. Natl. Acad. Sci. USA</i> 88:2274-2277, 1991	
		ERWIN <i>et al.</i> , "Macrophage-derived cell lines do not express proinflammatory cytokines after exposure to Bacillus anthracis lethal toxin," <i>Infection and Immunity</i> 69(2):1175-1177, 2001	
		EZZELL <i>et al.</i> , "Immunoelectrophoretic analysis, toxicity, and kinetics of in vitro production of the protective antigen and lethal factor components of Bacillus anthracis toxin," <i>Infection and Immunity</i> 45(3):761-767, 1984	
		FRIEDLANDER, "Protein kinase C activation has dissimilar effects on sodium-coupled uptakes in renal proximal tubular cells in primary culture," <i>The Journal of Biological Chemistry</i> 261(16):7123-7126, 1986	
		FRIEDLANDER <i>et al.</i> , "Characterization of macrophage sensitivity and resistance to anthrax lethal toxin," <i>Infection and Immunity</i> 61(1):245-252, 1993	
		GLASS <i>et al.</i> , "Nuclear receptor coactivators," <i>Current Opinion in Cell Biology</i> 9:222-232, 1997	
		GODOWSKI <i>et al.</i> , "Glucocorticoid receptor mutants that are constitutive activators of transcriptional enhancement," <i>Nature</i> 325(6102):365-368, 1987 (Abstract)	
		GOMEZ <i>et al.</i> , "Endogenous glucocorticoids attenuate Shiga toxin-2-induced toxicity in a mouse model of haemolytic uraemic syndrome," <i>Clin Exp Immunol</i> 131:217-224, 2003	
		HAMMOND <i>et al.</i> , "Lethal factor active-site mutations affect catalytic activity in vitro," <i>Infection and Immunity</i> 66(5):2374-2378, 1998	
		HANNA <i>et al.</i> , "Role of macrophage oxidative burst in the action of anthrax lethal toxin," <i>Molecular Medicine</i> 1(1):7-18, 1994	
		HANNA <i>et al.</i> , "Understanding Bacillus anthracis pathogenesis," <i>Trends in Microbiology</i> 7(5):180-182, 1999	
		HANNA, "Lethal toxin actions and their consequences," <i>Journal of Applied Microbiology</i> 87:285-287, 1999	
		HERRLICH, "Cross-talk between glucocorticoid receptor and AP-1," <i>Oncogene</i> 20:2465-2475, 2001	
		KARIN <i>et al.</i> , "AP-1--glucocorticoid receptor crosstalk taken to a higher level," <i>Journal of Endocrinology</i> 169:447-451, 2001	

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		KLEIN <i>et al.</i> , "Dual Nature of Resistance Mechanisms as Revealed by Studies of Anthrax Septicemia," <i>J. Bacteriol.</i> 85:1032-1038, 1963	
		KLIMPEL <i>et al.</i> , "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci. USA</i> 89:10277-10281, 1992	
		KLIMPEL <i>et al.</i> , "Anthrax toxin lethal factor contains a zinc metalloprotease consensus sequence which is required for lethal toxin activity," <i>Molecular Microbiology</i> 13(6):1093-1100, 1994	
		KOO <i>et al.</i> , "Apoptosis and melanogenesis in human melanoma cells induced by anthrax lethal factor inactivation of mitogen-activated protein kinase kinase," <i>PNAS</i> 99(5):3052-3057, 2002	
		KRSTIC <i>et al.</i> , "Mitogen-activated and cyclin-dependent protein kinases selectively and differentially modulate," <i>Molecular and Cellular Biology</i> 17(7):3947-3954, 1997	
		LEPPLA, "Production and purification of anthrax toxin," <i>Methods in Enzymology</i> 165:103-116, 1 st ed., Academic Press, 1998	
		LEPPLA, "Anthrax Toxin," <i>Handbook of Experimental Pharmacology</i> , Vol. 145, Chapter 19, pp. 445-472, 2000	
		LITTLE <i>et al.</i> , "Production and characterization of monoclonal antibodies against the lethal factor component of Bacillus anthracis lethal toxin," <i>Infection and Immunity</i> 58(6):1606-1613, 1990	
		LITTLE <i>et al.</i> , "Characterization of lethal factor binding and cell receptor binding domains of protective antigen of Bacillus anthracis using monoclonal antibodies," <i>Microbiology</i> 142:707-715, 1996	
		LOPEZ <i>et al.</i> , "Growth factors signal to steroid receptors through mitogen-activated protein kinase regulation of p160 coactivator activity," <i>The Journal of Biological Chemistry</i> 276(25):22177-22182, 2001	
		LUCIBELLO <i>et al.</i> , "Mutual transrepression of Fos and the glucocorticoid receptor: involvement of a functional domain in Fos which is absent in FosB," <i>The EMBO Journal</i> 9(9):2827-2834, 1990	
		KAU <i>et al.</i> , "Calyculin A sensitive protein phosphatase is required for Bacillus anthracis lethal toxin induced cytotoxicity," <i>Current Microbiology</i> 44:106-111, 2002	
		MACPHEE <i>et al.</i> , "Spontaneous recovery of rats from experimental allergic encephalomyelitis is dependent on regulation of the immune system by endogenous adrenal corticosteroids," <i>J. Exp. Med.</i> 169:431-445, 1989	

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		MCEWAN <i>et al.</i> , "Interaction of the human androgen receptor transactivation function with the general transcription factor TFIIF," <i>Proc. Natl. Acad. Sci. USA</i> 94:8485-8490, 1997	
		MCKENNA <i>et al.</i> , "Minireview: nuclear receptor coactivators--an update," <i>Endocrinology</i> 143(7):2461-2465, 2002	
		MIESFELD <i>et al.</i> , "Genetic complementation of a glucocorticoid receptor deficiency by expression of cloned receptor cDNA," <i>Cell</i> 46(3):389-399, 1986 (Abstract)	
		MIESFELD <i>et al.</i> , "Glucocorticoid receptor mutants that define a small region sufficient for enhancer activation," <i>Science</i> 236(4800):423-427, 1987 (Abstract)	
		NEECK <i>et al.</i> , "Neuroendocrine perturbations in fibromyalgia and chronic fatigue syndrome," <i>Neuroendocrine Mechanisms in Rheumatic Disease</i> 26(4):989-1002, 2000	
		PANNIFER <i>et al.</i> , "Crystal structure of the anthrax lethal factor," <i>Nature</i> 414:229-233, 2001	
		PELLIZZARI <i>et al.</i> , "Anthrax lethal factor cleaves MKK3 in macrophages and inhibits the LPS/IFN γ -induced release of NO and TNF α ," <i>FEBS Letters</i> 462:199-204, 1999	
		PELLIZZARI <i>et al.</i> , "Lethal factor of <i>Bacillus anthracis</i> cleaves the N-terminus of MAPKKs: analysis of the intracellular consequences in macrophages," <i>Int. J. Med. Microbiol.</i> 290:421-427, 2000	
		PEZARD <i>et al.</i> , "Contribution of individual toxin components to virulence of <i>Bacillus anthracis</i> ," <i>Infection and Immunity</i> 59(10):3472-3477, 1991	
		PRICE <i>et al.</i> , "Protection against anthrax lethal toxin challenge by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infection and Immunity</i> 69(7):4509-4515, 2001	
		QUINN <i>et al.</i> , "Functional mapping of anthrax toxin lethal factor by in-frame insertion mutagenesis," <i>The Journal of Biological Chemistry</i> 266(30):20124-20130, 1991	
		REICHARDT <i>et al.</i> , "Mice with an increased glucocorticoid receptor gene dosage show enhanced resistance to stress and endotoxic shock," <i>Molecular and Cellular Biology</i> 20(23):9009-9017, 2000	
		ROBERTS <i>et al.</i> , "Ltx1, a mouse locus that influences the susceptibility of macrophages to cytolysis caused by intoxication with <i>Bacillus anthracis</i> lethal factor, maps to chromosome 11," <i>Molecular Microbiology</i> 29(2):581-591, 1998	
		ROBERTSON <i>et al.</i> , "Molecular cloning and expression in <i>Escherichia coli</i> of the lethal factor gene of <i>Bacillus anthracis</i> ," <i>Gene</i> 44:71-78, 1986	

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		ROGATSKY <i>et al.</i> , "Antagonism of glucocorticoid receptor transcriptional activation by the c-Jun N-terminal kinase," <i>Proc. Natl. Acad. Sci. USA</i> 95(5):2050-2055, 1998	
		RUZEK <i>et al.</i> , "Endogenous glucocorticoids protect against cytokine-mediated lethality during viral infection," <i>The Journal of Immunology</i> 162:3527-3533, 1999	
		SCHMITT <i>et al.</i> , "Bacterial toxins: friends or foes?" <i>Emerging Infectious Diseases</i> 5(2):224-234, 1999	
		SCHÜLE <i>et al.</i> , "Functional antagonism between oncoprotein c-Jun and the glucocorticoid receptor," <i>Cell</i> 62:1217-1226, 1990	
		SHANKS <i>et al.</i> , "Mouse strain differences in plasma corticosterone following uncontrollable footshock," <i>Pharmacology Biochemistry & Behavior</i> 36:515-519, 1990	
		SHIN <i>et al.</i> , "Intracellular calcium antagonist protects cultured peritoneal macrophages against anthrax lethal toxin-induced cytotoxicity," <i>Cell Biology and Toxicology</i> 16:137-144, 2000	
		SINGH <i>et al.</i> , "Internalization and processing of Bacillus anthracis lethal toxin by toxin-sensitive and -resistant cells," <i>The Journal of Biological Chemistry</i> 264(19):11099-11102, 1989	
		SINGH <i>et al.</i> , "Oligomerization of anthrax toxin protective antigen and binding of lethal factor during endocytic uptake into mammalian cells," <i>Infection and Immunity</i> 67(4):1853-1859, 1999	
		STERNBERG <i>et al.</i> , "Inflammatory mediator-induced hypothalamic-pituitary-adrenal axis activation is defective in streptococcal cell wall arthritis-susceptible Lewis rats," <i>Proc. Natl. Acad. Sci. USA</i> 86:2374-2378, 1989	
		TANG <i>et al.</i> , "Proteasome activity is required for anthrax lethal toxin to kill macrophages," <i>Infection and Immunity</i> 67(6):3055-3060, 1999	
		VITALE <i>et al.</i> , "Susceptibility of mitogen-activated protein kinase family members to proteolysis by anthrax lethal factor," <i>Biochem. J.</i> 352:739-745, 2000	
		WADE <i>et al.</i> , "Anthrax toxin components stimulate chemotaxis of human polymorphonuclear neutrophils," <i>Proceedings of the Society for Experimental Biology and Medicine</i> , 179:159-162, 1985	
		WATTERS <i>et al.</i> , "Kif1C, a kinesin-like motor protein, mediates mouse macrophage resistance to anthrax lethal factor," <i>Current Biology</i> 11:1503-1511, 2001	
		WEBSTER <i>et al.</i> , "Neuroendocrine regulation of immunity," <i>Annu. Rev. Immunol.</i> 20:125-163, 2002	
		WEBSTER <i>et al.</i> , "Anthrax lethal factor represses glucocorticoid and progesterone receptor activity," <i>PNAS</i> 100(10):5706-5711, 2003	

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		WELKOS <i>et al.</i> , "Differences in susceptibility of inbred mice to <i>Bacillus anthracis</i> ," <i>Infection and Immunity</i> 51(3):795-800, 1986	
		ZUCKERMAN <i>et al.</i> , "In vivo inhibition of lipopolysaccharide-induced lethality and tumor necrosis factor synthesis by <i>Rhodobacter sphaeroides</i> diphosphoryl lipid A is dependent on corticosterone induction," <i>Infection and Immunity</i> 60(7):2581-2587, 1992	

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